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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,018	10/08/2003	Joan M. Fallon	8016-1 CIP CON	6224

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/681,018	FALLON, JOAN M.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-42* is/are pending in the application.

4a) Of the above claim(s) *36-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-35 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *23-42* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/8/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's election without traverse of Invention I, claims 23-35 and 42, filed on 06 October 2006 is acknowledged. Note, the restriction requirement made in the last Office Action is not a species election, as indicated in applicants response (the election of "the invention of *species I*"), rather, Group I and Group II inventions are two separate groups of inventions.

Applicant's amendment filed on 06 October 2006 is acknowledged and entered. Following the amendment, claim 42 is amended.

Currently, claims 23-42 are pending, and claims 23-35 and 42 are under consideration. Claims 36-41 are withdrawn from further consideration as being drawn to a non-elected invention.

Formal Matters:

Information Disclosure Statement

Applicant's IDS submitted on 10/8/03 is acknowledged and has been considered. A signed copy is attached hereto.

Priority acknowledgement

This application claims benefit of U.S. applications 09/703,395 filed on 11/7/00, and 09/466,559 filed on 12/17/99, which is acknowledged.

Abstract

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of *50 to 150 words*. It is important that the abstract *not exceed 150 words* in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Appropriate correction or a new abstract is required.

Specification

The specification is objected to because the status of U.S. Application 09/703,395, which has been issued as U.S. Patent No. 6,632,429, has not been updated yet.

Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 31, 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 27, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 31 is indefinite for the recitation "on a daily basis" as it is unclear whether it means one tablet per day, one tablet at a time more than one time per day, or something else. The metes and bounds of the claim, therefore, cannot be determined. Claim 33 is similarly indefinite.

Claim 33 is further indefinite for the recitation "an amount ..., determined according to the age" as it is unclear whether it is the same as "an effective amount" in the independent claim 23, and if it is not the same, what "an amount" is meant, and how it can be determined according to the age? Therefore, it is unclear what limit is intended, and metes and bounds of the claim cannot be determined.

Claim 34 is indefinite for the recitation "*at least about* three times per day" as it is unclear whether it means three times per day at the amount indicated in claim 33, or the amount indicated in claim 33, divided by 3? Further, it is unclear what range is covered by the term "about", is 2 times

or 4 times are considered "about three times", and what is the upper limit of the times of administration?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-35 and 42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a method for treating an individual having an autistic disorder with pathologic fecal chymotrypsin levels, does not reasonably provide enablement for claims to a method for treating any or all individuals having an autistic disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 23-35 and 42 are directed to a method for treating an autistic disorder with digestive enzymes, which reads on a method for treating any or all individuals having an autistic disorder. However, the specification merely discloses the treatment with digestive enzymes for autistic individuals with lowered pathologic fecal chymotrypsin levels (Exmple 6), and does not reasonably provide enablement commensurate in scope with claims to a method for treating all autistic individuals. Prior art search reveals that causes of autism are diverse and are not completely understood. For example, Happe et al. (Nat. Neurosci., 2006 Oct., 9(10):1218-20) reports that there is no single genetic or cognitive cause for the diverse symptoms defining autism, and that attempts at a single explanation for the symptoms of autism have failed (abstract). Belmonte et al. (Nat. Neurosci., 2006 Oct., 9(10):1221-5) reports that autism is an entirely behavioral diagnosis with no largely understood etiologies and no population-wide

biomarkers (abstract). Therefore, while lowered pathologic fecal chymotrypsin levels may be indicative for digestive enzyme therapy for certain autistic individuals, the prior art has not established, the instant applicants has disclosed that such a treatment would be beneficial for all autistic patients. Given the lack of fully understanding of the etiology of autism, and the reported diverse possible causes, it is completely unpredictable that said digestive enzyme therapy would be suitable for treating all individuals with autism, and it would require undue experimentation to practice the invention in a manner commensurate in scope with the claim.

Due to the large quantity of experimentation necessary to determine the autistic individuals suitable for the digestive enzyme therapy, and the significance of the treatment, the lack of specific direction/guidance presented in the specification regarding same, the absence of working examples directed to same (other than the patients with lowered pathologic fecal chymotrypsin levels), the complex nature of the invention, the state of the prior art indicating diverse etiology and lack of predictability and effective therapy, the breadth of the claims which embraces all autistic patients with any cause, undue experimentation would be required of the skilled artisan to use the claimed invention in its full scope.

Prior Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Horvath et al. (Journal of the Association for Academic Minority Physician, 1998, 9(1):9-15, provided by applicants) reports improved social and language skills in patients with autistic spectrum disorders after secretin administration.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
12/8/06